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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CROUCH, DEBORAH	
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1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/658,862	STOCKMAN CAMPBELL ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 1, 2005 and 21 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-171* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-171* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-00

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive. The amendment has been entered. Claims 89-171 are pending.

Claims 89-151, filed March 1, 2005, were entered and are presently of record. However the amendment was not responsive to the outstanding office action. These claims are examined in this office action.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states, "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 152-171 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 146-163 of copending Application No. 09/225,233. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. There is no distinction between the presently claimed nonhuman mammals and those of claims 146-163 in '233, although the particular methods are different. The particular method used does not affect the structure, function or use of the claimed nonhuman mammals.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 152-171 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U.S. Patent No. 6,525,243 B1 for reasons presented in the office action mailed November 26, 2003.

Claims 152-171 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,147,276 for reasons presented in the office action mailed November 26, 2004.

Claims are remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-18 of U.S. Patent No. 6,252,133 B1 for reasons set forth in the office action mailed May 9, 2003.

Applicant agreed to file a terminal disclaimer to U.S. Patent Nos. 6,525,243 B1, 6,147,276 and 6,252,133 B1 once allowable subject matter is identified.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 152-171 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 152-171 are to a live born clone of a pre-existing, non-embryonic, donor mammal from which a differentiated cell has been taken, wherein the mammal is selected from cattle, sheep, pigs, goats, mice rabbits, horses and rats and where the mammals are produced by nuclear transfer. However, the claimed mammals do not sufficiently

distinguish over pre-existing cattle, sheep, pigs, goats, mice and rabbits. Neither the claims nor the specification point out any characteristics of the claimed mammals that separate them from the pre-existing mammal. The method of making the mammals does not imbue any new or novel characteristic to the cloned mammals nor does the method imbue a new use to the mammals claimed. Further, the claims clearly state that the clone is a copy of a pre-existing mammal. Hence, the mammal as claimed is indistinguishable from the mammal as found in nature. Thus, the cloned nonhuman mammals of the claims is not seen as being "new" as required by 35 U.S.C. § 101.

Applicant argues that a clone of a pre-existing, non-embryonic, donor mammal is never found in nature because the clone is produced asexually. Applicant argues that nature does not make copies of such animals. Applicant argues that the clone is a copy or replica of a previously known mammal; it is not the same mammal because it occupies a different space and time than the previously known mammal. These arguments are not persuasive.

While a clone may be produced asexually, and applicant has discovered and developed a method of asexual reproduction of mammals, the product of the method, which is the presently claimed subject matter, is nonstatutory because it is a copy or replica of a prior existing mammal (cattle, sheep, pigs, goats, mice, rabbits, horses and rats). The method of producing the copy or replica does not affect the copy or replica. The gross structure, the function and the use of the copy or replica is the same as that of the pre-existing mammal that donated the nucleus used to produce the copy or replica, clone. There is no discernable difference that lends a patentable distinction between the clone and the pre-existing mammal, although the methods of producing them are different.

The clone and the pre-existing donor mammal can certainly occupy the same space and time, if both are alive at the same time. Further, occupying a different space and time is not a structural, functional or phenotypic characterization of the clone or the donor itself. The time and space the clone exists as compared to the donor mammal does not provide any new and useful property to the mammal. A mammal produced by in vitro fertilization can exist in a different time and space from the egg and sperm donor, but that property isn't a patentable distinction. Further, using applicant's time and space argument, all nonhuman mammals would be patentable over a pre-existing nonhuman mammal. This has not been the criterion applied for patentability regarding naturally occurring organisms, and it is not clear why it should be the standard for clones.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 152-171 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for clones of preexisting cattle, sheep, pigs and goats, does not reasonably provide enablement for clones of pre-existing mice, rabbits, horses and rats. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At the time of filing, the skilled artisan would have regarded the cloning of mice, rabbits, horses and rats to be unpredictable. Each used method steps not taught by the present specification.

Nuclear transfer in rabbits was successful only when surrogate females were asynchronous by 22 hours from recipient oocytes (Chesne, page 366, col. 1, parag. 1, lines 10-13 and page 367, col. 2, parag. 1). In reporting the birth of a cloned horse, Galli states that the success was aided by advances in assisted reproduction in the horse, including oocyte activation, when both protein synthesis and protein phosphorylation both must be inhibited and zona-free manipulation (Galli, page 635, col. 2, parag. 1, lines 7-13). Fitchev states that reconstituted rat embryos were transferred to the uterus of surrogate mothers but none developed to term (Fitchev, page 1528, col. 1, parag. 1, lines 1-3). The problem with rat somatic cell nuclear transfer is due to the spontaneous activation of rat oocytes within 30 minutes of their removal from the oviduct (Zhou, page 1179, col. 1, parag. 2, lines 5-10). Even when a "speedy" enucleation and transfer method was developed, no clones were born (Zhou, col. 2, lines 3-6 and parag. 1, lines 4-7). Successful cloning was reached when MG132, a protease inhibitor that reversibly blocks the first meiotic metaphase-anaphase transition in rat (Zhou, col. 2, parag. 2, lines 10-13). The method used in cloning mice included a prolonged interval between nuclear injection and oocyte activation, suppressing cytokinesis (Wakayama, page 373, lines 1-4). Each method for cloning rabbits, horses, rats and mice used steps materially different and separate from that disclosed in the specification. As the specification does not provide any guidance to the cloning of these species per se, and the ultimate methods were so different, the skilled artisan at the time of filing could not have relied upon the present specification to clone rabbits, horses, rats or mice. Thus, the skilled artisan would have needed to conduct an undue amount of experimentation without a predictable degree of success to implement the claimed invention for its entire breadth.

Claims 88-151 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are to a method for preparing a porcine embryo, a method of cloning a pig, a method for preparing a cloned porcine embryo, a method for preparing a porcine fetus and a method for preparing a porcine animal, each method by nuclear transfer. However, the specification does not provide evidence of conception by applicant at the time of filing. The term "porcine" is a broader term than pigs. Porcine encompasses species such as wild boars, whereas the term "pig" encompasses the typical farm animal. Further, there is no evidence of that applicant contemplated particular limitations of the claims. There is no description in the present specification for maturing porcine oocytes for 48 hrs prior to enucleation, transfer to a recipient porcine female, transfer to the uterine horn of a recipient porcine female, a diploid porcine differentiated cell, nonembryonic cells, culturing the nonembryonic cell in media containing LIF, FGF and/or stem cell factor, culture media comprising between 10 mM and 100 mM glucose, culture media comprising 25 mM glucose, obtaining cells from the genital ridge, transfer of a donor nucleus to an enucleated sow oocytes, maturing a sow oocytes for between 41 and 54 hours, activation in the presence of ionomycin, the porcine oocyte and recipient porcine female being asynchronous, the transfer embryo comprising 1 to 3 cells, activation with DMAP, any relation to estrus of the recipient and activation of the reconstructed embryo, or implanting a plurality of porcine embryos into the recipient female porcine. Without evidence of contemplation, there cannot be evidence that applicant was in possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention".

There is no reasonable clarity to those skilled in the art shown by reduction to practice, depiction in a drawing or description in sufficient detail that applicant had conceived of and was in possession of the subject matter of claims 88-151, as outlined above. Therefore, claims 88-151 lack written description and evidence of possession by applicant at the time of filing. To overcome this rejection, applicant can show by page and line number where support for the subject matter can be found.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skills in the art to which said subject matter pertains. patentability shall not be negatived by the manner in which the invention was made.

Claims 152-155, 163 and 164 (cattle) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

Sims teaches cloned bovines (page 6146, col. 1, parag. 2, lines 6-11). As the presently claimed cloned cattle do not exhibit a novel structural or functional difference from those described in Sims, Sims anticipates the claimed invention. In the alternative, the claimed cattle is obvious over Sims because there is no perceived structural or functional difference between the claimed cattle and the bovines of Sims. Thus, Sims either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 156, 163 and 165 (sheep) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McLaughlin et al (1990) Reproduction Fertil. Develop. 2, 619-622.

McLaughlin teaches cloned sheep (page 620, parag. 2-5, and page 621, parag. 1). As the presently claimed cloned sheep do not exhibit a novel structural or functional difference from those described in McLaughlin, McLaughlin anticipates the claimed invention. In the alternative, the claimed sheep is obvious over McLaughlin

because there is no perceived structural or functional difference between the claimed sheep and the sheep of McLaughlin. Thus, McLaughlin either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 157, 163 and 166 (pigs) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Prather et al (1989) Biology of Reproduction 41, 414-418.

Prather teaches a cloned pig (page 415, col.1, parag. 1 to page 416, line 8, and page 416, col. 2, lines 8-10). As the presently claimed cloned pigs do not exhibit a novel structural or functional difference from the pig described in Prather, Prather anticipates the claimed invention. In the alternative, the claimed pig is obvious over Prather because there is no perceived structural or functional difference between the claimed pigs and the pig of Prather. Thus, Prather either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660,

169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 158, 163 and 167 (goats) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yong et al (1991) Theriogenology 35, page 299.

Yong teaches cloned goats by nuclear transfer of the reconstituted goat embryos (parag. 2 and Table). As the presently claimed cloned goat does not exhibit a novel structural or functional difference from the goat described in Yong, Yong anticipates the claimed invention. In the alternative, the claimed goat is obvious over Prather because there is no perceived structural or functional difference between the claimed pig and the pig of Prather. Thus, Prather either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 159, 163 and 168 (mouse) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cheong et al (1993) Biology of Reproduct. 48, 958-963.

Cheong teaches cloned mice (page 959, col. 1, parag. 2 to col. 2, line 10 and page 962, Table 4). As the presently claimed cloned mouse does not exhibit a novel structural or functional difference from those described in Cheong, Cheong anticipates the claimed invention. In the alternative, the claimed mice are obvious over Cheong because there is no perceived structural or functional difference

between the claimed mouse and the mice of Cheong. Thus, Cheong either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 160, 163 and 169 (rabbits) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yang et al (1992) Biology of Reproduct. 47, 636-643.

Yang teaches cloned rabbits (page 640, col. 2, parags. 1 and 2, and page 642, Table 4). As the presently claimed cloned rabbit does not exhibit a novel structural or functional difference from those described in Yang, Yang anticipates the claimed invention. In the alternative, the claimed rabbit is are obvious over Yang because there is no perceived structural or functional difference between the claimed rabbit and the rabbits of Yang. Thus, Yang either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 161, 163 and 170 (horses) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lawrence et al (1993) The Journal of Nutrition 123, pp. 2152-2157.

Lawrence teaches standardbred mares and standardbred gelding (page 2153, col. 1, parag. 1, lines 1-4). As the presently claimed cloned horse does not exhibit a novel structural or functional differences from those described in Lawrence, Lawrence anticipates the claimed invention. In the alternative, the claimed horse is obvious over Lawrence because there is no perceived structural or functional difference between the horses. Thus, Lawrence either anticipates or makes obvious the claimed invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 152-154, 162, 163 and 171 (rats) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gonzales-Pacheco et al (1993) The Journal of Nutrition 123, 90-97.

Gonzales-Pacheco teaches male Fisher 34/NHsd and Harlan Sprague Dawley rats (page 91, col. 1, parag. 2, lines 1-3). As the presently claimed cloned rat does not exhibit a novel structural or functional differences from those described in Gonzales-Pacheco, Gonzales-Pacheco anticipates the claimed invention. In the alternative, the claimed horse is obvious over Gonzales-Pancheo because there is no

perceived structural or functional difference between the rats. Thus, Gonzales-Pacheco either anticipates or makes obvious the claimed invention.

Applicant argues that the cited art is missing a limitation of the claimed mammals, namely, one of the mammals is not a clone or a pre-existing, non-embryonic, non-foetal, donor mammal. Applicant argues that the cited prior art does not make the cloned mammals claimed obvious because there is no teaching or suggestion that one of the animals is a clone. These arguments are not persuasive.

A clone of the present claims is not seen as being materially different and separate from the cited art in this office action. Being a clone is not described as providing any novel or nonobvious structural or functional differences over the structural or functional features of mammals of the cited art. The clones and the mammals are of the same uses. Applicant's method is unique in that it permits the replication or reproduction of the same mammal. However, a method of making a product does not make a product, already known in the art, to be patentable unless there is some distinction to the product. This is not the case here. The cloned mammals are in very way the same, and by same this is structural and functional sameness, as the mammals of the art. The mammals cited in the prior art make obvious, or anticipate, the claimed clones because products are deemed as being patentably different.

Applicant argues that a distinguishing feature of their claimed mammals is that the clone creates a situation that never existed prior to applicant's invention, the existence of a non-embryonic, non-foetal, donor mammal prior to the existence of a clone of that mammal. Applicant argues that one is physically able to examine applicant's donor mammal prior to the generation of a clone of that mammal. Applicant argues that the benefits are readily apparent and cannot be considered obvious from the animals found in the art. These arguments are not persuasive.

Still, applicant has not offered persuasive arguments or evidence that the cloned mammal differs materially from the "original" mammal. In this regard, the method of producing the clone by nuclear transfer has not altered the clone in anyway that provides patentable distinction. As stated above a new method of producing a known product does not provide patentability to the product unless there is a novel and nonobvious property to the product. Nuclear transfer does not provide such a property. Also, it is noted that one can physically examine the donor mammal only in those instances when the donor animal is alive at the time of nuclear donation, or cell sampling. The benefits are gleaned from the method of nuclear transfer used to make the cloned mammals and do not alter a benefit to or from the clones, per se.

Applicant argue that the donor and the progeny have the same set of chromosomes. Applicant argues that this is different from sexual reproduction in which progeny receives half of its chromosomes for each parent. Applicant argues that this property allows one to distinguish between clones and sexually produced mammals. These arguments are not persuasive.

Same set of chromosomes is not defined in the specification, and is thus open to reasonable interpretation. Same set of chromosomes can also mean the same number of chromosomes. It can mean the very same set, but this is unlikely given the replication necessary in tissue growth. It can mean the same nucleotide sequence in total, with no variation, not on nucleotide difference. Actually, applicant has not defined on this record what is meant by same set of chromosomes. Thus, what exactly applicant means is not clear. Further, applicant does not state how one would determine the same set of chromosomes present in a donor mammal and a clone, or how one would know when two animals had the same set of chromosomes. In addition, applicant argues parent as a reference point for comparison. However,

the specification does not define parent. Thus, it is not known if applicant by parent means the nuclear donor mammal or the surrogate female.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

August 15, 2005